



DEPARTMENT OF HEALTH & HUMAN SERVICES

g4107d
Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 31 2003

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Brian Petruzzi
115 N. Jefferson Avenue
First Floor
Margate, NJ 08402

Ref. No: 03-HFD-312-04

Dear Mr. Petruzzi:

This letter is written in reference to your firm's marketing of various products that are promoted on your Internet web site, www.legal-marijuana-alternatives.com, as alternatives to illicit street drugs. Some of these products purport to contain sources of ephedrine (i.e., ephedra, ma huang, or sida cordifolia).

Your Internet web site, from which these products may be ordered, promotes these products with brand names and claims indicating that they are intended to be used as street drug alternatives, and lists ingredients of these products, as follows:

- Red Dawn a.k.a Trip2Nite capsules

"SO CLOSE TO E YOU'LL THINK IT IS"

"Weren't happy with herbal ecstasy? Give this a shot, you will eat your words. This is similar to the old Midnight herbal Ecstasy product except 1 capsule of Red Dawn equals about 3 Midnight herbal Ecstasy! The best new herbal alternative to Herbal Ecstasy! According to our customers, this is BY FAR the 'best herbal ecstasy alternative product on the Market today,' and our Best Herbal Pill Period, 10 times better than Herbal Ecstasy. Just a much more natural enjoyable feeling!... Are you ready to 'put your faith' back into legal herbal alternatives? Than [sic] purchase Red Dawn today! 100% legal Natural Herbal Ingredients: Ma Huang, Guarana, 5-HTP, Bioperidine, Indian Bromine, Cinnamon, Cola Nut, Niacin, Fo Ti. 9 VERY effective... According to our customers, The best legal experience of their life... Trip2Night- the BEST 100% legal herbal Euphoric Product on earth..."

- **Herbal Ecstasy Organic (ephedra free!) pills**

"The Strongest LEGAL herbal Ecstasy brand product... This is the real thing. New Ephedrine Free Formula! Accept no imitations. (trademark product must have (e) on each pill.) The strongest pure ecstasy alternative the Ecstasy Company makes. If you want MDMA effects without subjecting your brain to chemicals, this is a safe bet. You will feel the energizing and euphoric effects with the first dose. Ingredients: Sida Cordifolia [sic], including German Wild Ginko [sic] Biloba, African Raw Cola Nut, Russian Gotu-Kola, Indonesian Wild, Fo-Ti-Tient, Green Tea Extract, Rou Gui (Rare Chinese Nutmeg)... For maximum effect alcoholic [sic] beverages may enhance the effect. This product will last for up to 4 hours creating euphoric sensations... Because of our concentrated process, we have enhanced the power of the herbs making herbal ecstasy stronger than any herbal high product on the market."

- **Space Cadets pills**

"Space Cadets are an uplifting natural and legal psychedelic, that will take you to another dimension... Space Cadets contain a mind expanding mix of a natural source of spiritual herbal extracts, together with herbal stimulants, to take you to a new realm of consciousness. Giggly, surreal, and paranoia free. A Truly INCREDIBLE legal experience."

- **Blueberry MATRIX pills**

"Calm your nerves... relieve your stress... The relaxed mellow buzz is hard to describe but we will try. A wonderful herbal alternative to dangerous RX drugs like Xanax or Valium... This is an excellent product and is very effective while remaining 100% legal. It is composed of strong extracts of kava, valerian, and wild berry... Excellent for minor pain, anxiety, insomnia and just for feeling extremely relaxed and stress free... This product knocks all the other herbal sedatives out of the water. This is the best herbal combination geared for FULL BODY relaxation we have EVER seen... you WILL NOT FIND A BETTER LEGAL HERBAL RELAXATION/NERVE-Calming RX ALTERNATIVE! This is the product you have been waiting for!!! Ingredients: 5-HTP extract 10X, Pheneproxolamine, Valerian Root Extract 10X, Wild Berry extract 10X, Kava Kava extract 10X and Bioperine."

- **Magic Mushrooms II pills**

"A Magical Mystical Journey, IN A PILL! 100% better than Magic Mushrooms One... Everyone has different reactions to these. To some it is real relaxing like a

xanax or a muscle relaxer/painkiller, others say that feel like real shrooms which is full of energy and vitality... The variety and length of the effects differ with each individuals metabolism... Magic Mushrooms' includes: Black antler reshi Mushrooms, Brazilian Guarana, Tunera diffusa, Ancient mexican witching herb Scutellaria laterfolia, Ganoderma lucidem, Myristica fragans."

- **Tribal Visions (mushroom formula)**

"Formulated from rare herbs used by psychonauts and shamans during tribal rituals. 'This stuff is the BOMB!' Contains: Yohimbe, Kava Kava, Wild Lettuce, Marapuama extract, Shiitake mushroom, Hawthorne extract, Gotu Kola, Damiana, Cordyceps mushroom, Kava Kava extract, Ginko Biloba extract."

FDA is aware that some street drug alternatives are being marketed as dietary supplements. FDA does not believe that street drug alternatives are intended to be used to augment the diet to promote health or reduce the risk of disease. Accordingly, street drug alternatives are not intended to supplement the diet and are not dietary supplements. In March of 2000, FDA made available a guidance for industry on street drug alternatives. This document contains additional information and is available at <http://www.fda.gov/cder/guidance/index.htm>.

Based on the claims cited, the products discussed above are "drugs" as defined in Section 201(g) of the Federal Food, Drug, and Cosmetic Act (Act). Moreover, they are also "new drugs" (Section 201(p) of the Act) because there is no evidence that these products are generally recognized as safe and effective for their intended uses. Under Section 505 of the Act, a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved new drug application (NDA) is in effect for such drug. Since these products are not the subjects of approved NDAs, they may not be marketed in the United States and their continued marketing violates Section 505 of the Act.

This letter is not intended to be an all-inclusive review of your Internet web site or all of your firm's labeling and products, and it is not intended to be an all-inclusive list of violations concerning your firm and its products. You are responsible for ensuring that all products marketed by your firm are in compliance with applicable United States laws.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act

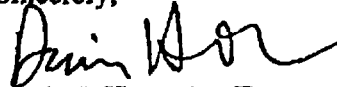
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provides for seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

You must notify this office in writing within fifteen (15) working days of your receipt of this letter as to the specific actions you have taken to correct the stated violations. You should also include an explanation of each step you have taken to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be made. Further, if your firm does not manufacture the product, your reply should also include the name and address of the manufacturer. If the firm from which you receive the product is not the manufacturer, please include the name of your supplier in addition to the manufacturing firm.

Address your reply to the Food and Drug Administration, Division of New Drugs and Labeling Compliance, 5600 Fishers Lane, (HFD-310 / MM2 / Rm. 328), Rockville, MD 20857, Attention: Dr. Linda Silvers.

Sincerely,



David J. Horowitz, Esq.

Director

Office of Compliance

Center for Drug Evaluation and Research

cc:
Domain Registration
70 Blanchard Rd.
Burlington, MA 01803